DELETION OF INVENTORS

Please correct the inventorship under 37 CFR §1.48(b) by removing the following inventors from the present application:

Luc Desnoyers, Timothy L. Stewart and Zemin Zhang.

REMARKS

Upon entry of the foregoing amendments to the specification, the title has been amended. Also, the specification has been amended as shown above to remove URLs from the specification. No new matter has been added by the amendments to the title or the specification.

The claims have been amended as set forth above. Upon entry of the above-described amendments and new claims, Claims 22, 26-29 and 32-44 are pending. Claims 23-25 and 30-31 have been cancelled without prejudice toward future prosecution. Claims 22 and 26-29 have been amended to remove reference to the Figures. Claim 22 has been amended to recite 98% amino acid sequence identity. Support for the amendment is found at page 73, lines 13-14. Also, Claim 22 and 26 have been amended to add the limitation that the claimed polypeptide has the ability to induce mesangial cell proliferation or to induce fetal hemoglobin. Support for this amendment is found in Examples 40 and 41 on page 168, describing a mesangial cell proliferation assay (Assay #92) and fetal hemoglobin induction assay (Assay #107). Claim 34 has been amended as set forth above. Exemplary support for the amendment to Claim 34 is found at page 80, lines 23-29. New Claims 35-44 have been added. The new claims are supported by the original claims and specification as filed. Thus, no new matter is added by the amendments and the claims are fully supported by the specification as originally filed.

Applicants respond below to the specific rejections raised by the PTO in the Office Action mailed March 29, 2005. For the reasons set forth below, Applicants respectfully traverse.

Correction of Inventorship under 37 CFR §1.48(b)

Applicants request that several inventors be deleted, as these inventors' inventions are no longer being claimed in the present application as a result of prosecution. The fee as set forth in § 1.17(i) is submitted herewith.

Information Disclosure Statement

The Examiner states that the previously-filed information disclosure statements have been considered, but do not give sufficient identifying information to determine if the sequences constitute prior art.

Applicants submit herewith an Information Disclosure Statement that includes more detailed information regarding the BLAST results, including the publication date of the relevant sequences.

Specification

The Examiner states a new title is required that is more clearly indicative of the invention to which the claims are directed. The title has been amended to recite "POLYPEPTIDES THAT INDUCE CELL PROLIFERATION OR INDUCE FETAL HEMOGLOBIN."

Also, the Examiner states that the specification should be reviewed for the recitation of improper hyperlinks, and that all such recitations should be deleted or amended. Applicants have amended the specification to address the Examiner's concern. In particular, Applicants have replaced the hyperlinks with text that describes the location of the websites. The amended text no longer constitutes browser executable code.

Rejections under 35 U.S.C. §112, first paragraph – Enablement

The Examiner has rejected Claims 22-27 and 30-34 as lacking enablement. The Examiner argues that the claims encompass an unreasonable number of inoperative polypeptide sequences, which the skilled artisan would not know how to use. The Examiner argues that the specification does not provide guidance for using polypeptides related (i.e., 80%-99% identity), but not identical to SEQ ID NO:61, which do not have the activities that PRO4408 is asserted to have.

As set forth above, Claims 22 and 26 have been amended to recite the functional limitation "wherein said isolated polypeptide has the ability to induce mesangial cell proliferation or to induce fetal hemoglobin." In view of this, the specification teaches how to make and use the claimed subject matter. Specifically, as acknowledged by the Examiner, the specification describes how to make the claimed variant polypeptides (for example, see page 109, line 7 to page 111, line 16). Furthermore, one of skill in the art would know how to follow Example 40 or Example 41 to assay for the claimed function in the variant polypeptides. Based upon that teaching, one skilled in the art would know how to make and use the full scope of the claimed subject matter.

Therefore, Applicants request that the Examiner reconsider and withdraw the enablement rejection under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. §112, first paragraph – Deposit Requirements

Claims 22-27 and 30-34 are rejected as not complying with the enablement requirement, since the deposit requirements were not met. The Examiner requests a statement that the deposit "will be maintained for a term of at least 30 years and at least five (5) years after the most recent request for the furnishing of sample of the deposit was received by the depository."

Respectfully, this requirement has already been met. As noted by the Examiner, the deposit was made under the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure and the Regulations thereunder (Budapest Treaty). However, the Examiner argues that this statement only provides partial compliance with the deposit requirement and requests the above statement. Applicants assert that they have fully complied with the requirement by stating that the deposit was made under the provisions of the Budapest Treaty because deposit under the Treaty universally requires that the depositor agree not to withdraw the deposited material for a period of five years after the most recent request for a sample, and in any case at least 30 years after deposit (per Rule 9.1).

Nonetheless, enclosed is a Declaration under 37 C.F.R. §1.808 that states that the deposit will be maintained for a term of at least 30 years and at least five (5) years after the most recent request for the furnishing of sample of the deposit was received by the depository.

Rejections under 35 U.S.C. §112, first paragraph – Written Description

The Examiner asserts that Claims 22-27, 30-31 and 33-34 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner argues that "[t]he claims do not require that the claimed polypeptides possess any particular biological activity." The Examiner further argues that the "claims are broad because they do not require the claimed polypeptide to be identical to the disclosed sequence and because the claims have no functional limitation."

The Legal Standard for Written Description

The well-established test for sufficiency of support under the written description requirement of 35 U.S.C. §112 , first paragraph is whether the disclosure "reasonably conveys to artisan that the inventor had possession at that time of the later claimed subject matter." *In re Kaslow*, 707 F.2d 1366, 1375, 2121 USPQ 1089, 1096 (Fed. Cir. 1983); *see also Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at1563, 19 USPQ2d at 1116 (Fed. Cir. 1991). The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis. *See e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991). The factual determination in a written description analysis depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. *Union Oil v. Atlantic Richfield Co.*, 208 F.3d 989, 996 (Fed. Cir. 2000).

Applicants have amended Claims 22 and 26 to recite that the claimed variant polypeptides have "the ability to induce mesangial cell proliferation or to induce fetal hemoglobin." Accordingly, Applicants maintain that the claims recite sufficient distinguishing characteristics for the claimed genus of polypeptides. Based on the detailed description of the cloning and expression of variants of PRO4408 in the specification, the description of the assays in Examples 40 and 41, the actual reduction to practice of sequences SEQ ID NOs: 60 and 61, and the functional recitation in the instant claims, Applicants submit that one of skill in the art would know that Applicants possessed the invention as claimed in the instant claims. Hence, Applicants respectfully request that the PTO reconsider and withdraw the written description rejection under 35 U.S.C. §112.

Rejections under 35 U.S.C. §112, second paragraph

The Examiner has rejected Claims 22-27 and 30-34 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner states that "[c]laims that recite 'extracellular domain' are indefinite as no extracellular domain has been described." Further according to the Examiner, if the polypeptide possesses an extracellular domain, the recitation of "the extracellular domain ... lacking its associated signal sequence" is indefinite because a signal sequence is general not considered to be part of an extracellular domain.

As set forth above, Applicants have removed reference to the extracellular domain from the claims. Therefore, this rejection is moot and its withdrawal is requested.

Rejection under 35 U.S.C. §102 – Anticipation

U.S. Patent Nos. 6,063,767 and 5,888,742:

The Examiner has rejected Claims 22-25 and 33-34 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Nos. 6,063,767 and 5,888,742. The '767 patent is a divisional of the '742 patent. The Examiner argues that SEQ ID NO:3 from the cited patents is 98.1% identical to the instant SEQ ID NO:61. Respectfully, Applicants argue that the '767 and '742 patents do not anticipate the claims as amended.

Applicants disagree with the Examiner that the SEQ ID NO:3 from the cited patents is 98.1% identical to SEQ ID NO:61. For example, as set forth in the specification at page 74, lines 6-22, amino acid sequence identity is determined by dividing the number of identical amino acids between the two sequences by the total number of amino acids in the PRO polypeptide, which in this case is SEQ ID NO:61 (223 amino acids), and multiplying that number by 100. According to Applicants' alignment, the two sequences have 218 identical amino acids. Thus, the identity is 218/223 x 100, which equals 97.8%.

Therefore, '767 patent and the '742 patent do not anticipate the amended claims because neither discloses an isolated polypeptide having at least 98% amino acid sequence identity to the amino acid sequence of the polypeptide of SEQ ID NO:61; the amino acid sequence of the polypeptide of SEQ ID NO:61, lacking its associated signal peptide; or the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 203971.

WO 99/31236 and WO 99/53051:

The Examiner also rejected Claims 22-25 under 35 U.S.C. §102(a) as being anticipated by WO 99/31236 and WO 99/53051. The Examiner argues that SEQ ID NO:225 from WO 99/31236 and SEQ ID NO:8 from WO 99/53051 each are 97.8% identical to SEQ ID NO:61. Neither publication anticipates any of the claims because neither discloses an isolated polypeptide having at least 98% amino acid sequence identity to the amino acid sequence of the polypeptide of SEQ ID NO:61; the amino acid sequence of the polypeptide of SEQ ID NO:61,

lacking its associated signal peptide; or the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 203971.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102 because none of the cited references teaches each and every element of the claims.

Conclusion

The present application is believed to be in condition for allowance, and an early action to that effect is respectfully solicited. Applicants invite the Examiner to call the undersigned if any issues may be resolved through a telephonic conversation.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 28, 2005

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